**STATEMENT**

**BY**

**MICHAEL FRIEDMAN, M.D.**

**LEAD DEPUTY COMMISSIONER**

**FOOD AND DRUG ADMINISTRATION**

**PUBLIC HEALTH SERVICE**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

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INTRODUCTION

Good morning, Mr. Chairman and Members of the Subcommittee. My name is Dr. Michael Friedman. I am the Lead Deputy Commissioner for the Food and Drug Administration (FDA). I am pleased to be here today to participate in a discussion of the FDA's Medical Device Program, which is managed by the Center for Devices and Radiological Health (CDRH). As the Congress prepares to debate possible revision of the Federal Food, Drug, and Cosmetic Act (the Act), it is essential that everyone have a complete and accurate understanding of the program in order to make positive improvements and to assess the full impact of suggested changes. We are ready to assist you in that regard.

Today we have been asked to provide basic information about medical devices, the Agency's regulation of these devices and the import to patients of such available medical devices. We are aware that this is the first of the device hearings that you will hold. We understand that at a later hearing the Committee will focus on the administrative and regulatory reforms the Agency has already implemented as well as those being actively considered, which represent improvements in the Medical Device Program, and potential changes to the medical device law.

**WHAT IS A MEDICAL DEVICE?**

In 1938 when the Act was passed, medical devices, for the most part, were simple instruments such as stethoscopes and scalpels in which defects would be readily apparent. The technology boom after World War II, and later the spin-off from the fertile industrial environment that made possible NASA and cold war weapons research, greatly increased the number and complexity of medical devices, including landmark products such as heart-lung machines and dialysis equipment.

According to the technical definition now found in the Act, a "device" is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory, which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body and which does not achieve its primary intended purposes through chemical action and which is not dependent upon being metabolized for the achievement of its primary intended purposes."

As this definition suggests, many different types of products are properly regulated as medical devices. Medical devices include over 100,000 products in more than 1,700 categories. These range from simple everyday articles such as thermometers, tongue depressors, and heating pads, to the more complex devices such as pacemakers, intrauterine devices, fetal stents and kidney dialysis machines.

Although some of the earliest medical devices (e.g. bandages) have retained their same basic form and function, the complexity and use of medical devices have increased exponentially over the past 50 years. Devices are more sophisticated, more dependable and more convenient. Patient care has improved dramatically as a result of these changes. The following examples illustrate advances that have been made in medical technology in just the last few years.

- Heart defibrillators have progressed from large, bulky external pumps to small external machines to totally implantable devices--about the same size as a pacemaker of a few years ago.

- Surgical tools enable us to operate on a fetus in utero.

- Open heart surgery once required for coronary artery disease has been largely replaced by less invasive techniques such as balloon angioplasty, insertion of cardiovascular stents, laser ablation of plaque and minimally invasive surgery.

- “Artificial" skin for burn victims is now available.

- Many major surgical procedures (e.g., removal of the gallbladder) have been replaced with laproscopic procedures that require only small incisions. This "revolution" alone has dramatically reduced hospital stays and recuperation is much faster.

- Traditional surgery for Benign Prostatic Hyperplasia often had significant bleeding, required indwelling catheters, and was complicated by incontinence and impotence in many patients. We now have new therapies that require less anesthesia, cause less blood loss, and are associated with significantly less incontinence and impotence.

- New devices have been developed to do needle biopsy of breast abnormalities without general anesthesia or major surgery.

- Many diagnostic devices now can be used at home--e.g., testing for blood clotting, pregnancy, cholesterol, glucose.

- Improvements to anesthesia systems have reduced risks to patients several-fold.

- New imaging systems (PET and MRI) provide a dramatic improvement in image quality, information content and analysis.

- Cemented joint replacements for hips have given way to better functioning, more durable replacements, not just for hip problems but for nearly every joint in the body.

In the last year alone, FDA has approved several breakthrough devices. The Thoratec Ventricular Assist Device System, for example, is a pump that assists the heart in patients who are waiting for a heart transplant and are at imminent risk of dying before a donor heart is available; the Ultramark 9 High Definition Ultrasound System is a first-of-a-kind device to aid the physician in differentiating benign from malignant breast lesions; the PAPNET Testing System is an aid in rescreening Pap smears previously reported as negative.

As diverse as medical devices are, so are the range and complexity of problems that can arise from their use. These problems include mechanical failure, faulty design, poor manufacturing quality, adverse effects of materials implanted in the body, improper maintenance/specifications, user error, compromised sterility/shelf life and electromagnetic interference among devices. Examples of injuries resulting from use of medical devices include bone disintegration caused by the material used in temporomandibular jaw implants; patient deaths caused by fractures in implanted artificial heart valves; and electrocution of babies when apnea monitor leads were mistakenly plugged into wall outlets.

**UNDER WHAT AUTHORITIES DO WE PRESENTLY OPERATE ?**

The 1938 Act initially charged FDA with removing adulterated or misbranded medical devices from the market. It did not give the Agency the authority to review medical devices before entering the market. Changes were made in the Act in 1976 after a commission determined that more than 700 deaths and 10,000 injuries were associated with medical devices. Among other injuries and deaths, 512 deaths and injuries were attributed to

heart valves, 89 deaths and 186 injuries were tied to heart pacemakers and ten deaths and 8,000 injuries were attributed to intrauterine devices. (Cooper Commission, Medical Devices, A Legislative Plan, September 1970).

After concluding that the Act did not provide sufficient authority for the FDA adequately to protect the public health with respect to medical devices, the Medical Device Amendments of 1976 were passed (1976 Amendments). (Public Law 94-295)

The 1976 Amendments provided several mechanisms to achieve this goal, including classification of medical devices, device listing, establishment registration, adherence to Good Manufacturing Practices (GMPs), and extensive control over market introduction of medical devices. The Safe Medical Devices Act of 1990 (Public Law 101-629)and the Medical Device Amendments of 1992 (Public Law 102-300) revised and expanded the 1976 Act.

The Agency carries out its medical device responsibilities by:

- evaluating new products before they are marketed for conformance to requisite design features and standards,

engineering bench tests, and, as needed, data from animal trials or clinical trials in patients;

- assuring quality systems are in place in the device manufacturing plants--through inspection and enforcement activities; and,

- collecting and monitoring adverse effects from marketed products and investigations, and taking action, when necessary, to prevent injury or death.

The process provides for orderly development of new devices starting with bench and animal tests, moving next through scientifically sound clinical investigations, and, only after independent review of the results, approval for marketing. This system has three goals: (1) to screen out bad ideas and products that are unsafe or don't produce a benefit; (2) to provide early feedback in order to detect and fix design or manufacturing flaws; and (3) to give doctors and patients an accurate interpretable experience from which to determine in whom to use a device, what to expect from its use, and how to avoid a prolonged learning curve using it (so that patients benefit).

Let me describe a few examples of how this process serves the health needs of the American consumers. Several years ago, Shiley was re-designing its 60 degree heart valve to open to 70 degrees. They were trying to reduce the chance of blood clots and risk of stroke. Our reviewers did not approve Shiley's application because it did not have an engineering metal stress analysis nor any clinical data. But, in Europe, the 70 degree valve was approved for marketing, used in thousands of patients, and turned out to break about six times as often as the 60 degree valve.

In the last three years, one of the world's most sophisticated device companies developed a new pacemaker that, during clinical studies, was found to have a microprocessor design flaw. Approximately one in every few hundred patients would have his heart paced at 200 beats per minute. Because this design defect was discovered during clinical trials, the company was able to re-design the product before it was marketed and used by thousands of patients in the United States.

Another company designed a new stent that was smaller and more flexible than existing products so it could be used in convoluted and narrow heart arteries. The device was approved

for marketing in Europe and at least one other country. During FDA review of the device, our engineers identified a design feature which caused metal fatigue and breakage. The company subsequently re-designed the stent before clinical trials were underway in this country.

In a similar situation, a design/ manufacturing defect in an implanted pacemaker/defibrillator caused corrosion which resulted in it stopping pacing in up to ten percent of patients. When this was discovered, marketing of the device was stopped in Europe and the product was re-designed prior to availability of the device in the U.S.

CDRH is responsible for carrying out an electronic product radiation control program designed to protect the public health and safety from electronic product radiation under the 1968 Radiation Control for Health and Safety Act (Public Law 90-602). CDRH also is responsible for implementation of the Mammography Quality Standards Act of 1992 (MQSA) (Public Law 102-539) which requires the establishment of a Federal certification and inspection program for mammography facilities; regulations and standards for accrediting bodies for mammography facilities; and standards for mammography

equipment, personnel, and practices, including quality assurance.

**EVALUATING NEW DEVICES BEFORE THEY ARE MARKETED**.

Because of the diverse nature of devices and the device industry, we have a product approval system with special characteristics. There is a classification system of products based on the degree of risk and the need for information on use of the device in patients.

Devices on the market at the time the original law was passed were assigned to one of three "classes." Those presenting the least risk, such as elastic bandages, were placed in Class I and subject to "general controls." General controls include registration and listing, prohibitions against adulteration and misbranding, notification, repair/replace/ refund, recall, records and reports, and adherence to Good Manufacturing Practices (GMPs). Although a number of Class I devices still require premarket notification, approximately three-fourths are low risk devices that FDA has exempted from premarket notification. Examples of such devices include

oxygen masks and manual surgical instruments such as scalpels and tissue retractors.

Class II devices, presenting greater concern, are subject to "special controls" such as postmarket surveillance studies and performance standards, in addition to the general controls. On the risk spectrum these are the next category of devices about which the technology is well understood but we need to review data about the performance of the device, usually through bench test data.

The highest risk devices are those that represent new technology. These are Class III devices, which include many implanted and life-supporting or life-sustaining devices, are subject to more stringent controls and requirements, including premarket review. For these devices, comprehensive evaluation, including data from clinical studies, is required to ensure safety and effectiveness. This involves bench and animal tests, clinical trials, the submission of a Premarket Approval Application (PMA), and in many cases review by an outside advisory panel. Class III devices comprise fewer than 1% of marketing applications received by the agency. Examples of

devices in this category include heart valves, implantable defibrillators, and computerized microscopes that automatically read Pap smears.

Devices on the market when the Amendments were passed that have been placed in Class III do not require premarket approval until the Agency issues a regulation subjecting them to that requirement. New devices are classified automatically into Class III and require approval unless they are either shown to be substantially equivalent to another device for which premarket approval is not required or they are reclassified. The vast majority of devices (approximately 98%) enter the market through this premarket notification process. Examples include hearing aids; hip implants; CT, ultrasound, x-ray, and MRI imaging devices; and surgical lasers.

## QUALITY SYSTEMS FOR DEVICE MANUFACTURERS

FDA inspects manufacturing facilities to be sure they are in compliance with “good manufacturing practices” (GMPs). Last October, FDA published a quality system regulation (21 CFR Parts 808, 812 and 820) which revised GMPs by adding design control requirements. The new quality systems regulation will

enhance consumer protection by reducing the number of recalls from poorly designed devices and resultant patient injuries. It has been estimated that nearly half of the 1200 device product recalls conducted annually are attributed to device design. The new regulations also are consistent with quality system requirements worldwide; this meets an important goal of global harmonization.

**POSTMARKET ADVERSE EVENTS REPORTING**

Postmarket surveillance of already-marketed devices is a vital complement to the premarket review program, because no system of premarket review, no matter how thorough, can prevent all potential safety problems once a device is in widespread use. Postmarketing reporting is a system through which the Agency receives reports of serious adverse events. Such reporting forms the basis for corrective actions by the Agency, which includes warnings to users and product recalls. FDA now receives over 100,000 adverse event reports annually from manufacturers, hospitals, health professionals and consumers.

The regulation of medical devices presents unique challenges. To address these challenges requires both breadth and depth of scientific capabilities. The FDA must maintain staffing and

expertise of the following scientists in order to keep pace with advances:

- Engineers (including biomedical, electrical/ electronics, and materials).
- Biologists and microbiologists
- Physicians and other clinicians
- Chemists, biochemists and toxicologists
- Medical technologists
- Physicists
- Statisticians
- Consumer safety officers and field investigators
- Human factors specialists

**WHERE IS THE AGENCY TODAY?**

Over the past few years, CDRH has worked hard to streamline the regulatory processes for medical devices and has implemented a number of management initiatives aimed at ensuring that it would function more efficiently and effectively. As a result of these efforts the review times for medical devices have dramatically improved.

In Fiscal Year 1996, CDRH improved its review times for PMAs, which are the full safety and efficacy submissions required for

novel or high risk devices. In Fiscal Year 1996, CDRH approved 43 PMAs, a six year high, and of these, 24 were major new products, an all-time high.

Eight of the 15 PMAs submitted to the Agency in the first half of Fiscal Year 1996, received a first action within the 180-day statutory deadline. This performance was significantly better than in 1994 or 1995.

In addition, the PMA approval time in Fiscal Year 1997 has decreased by 25 to 30 percent compared to any of the last three years. Nonetheless, we are not satisfied and CDRH and the Agency are focusing now on further improvements in the PMA review times, just as we have done for new drug applications.

CDRH also has made notable progress over the last three years in reducing review times for 510(k) applications, the abbreviated submissions. In Fiscal Year 1996, the median review time for devices that received a finding of substantial equivalence was 85 days. These reviews were completed in nearly half the time as the peak of 144 days in fiscal year 1993. The average 510(k) review time in Fiscal Year 1996 was 110 days, down from the peak of 184 days in Fiscal Year 1994.

Moreover, the 510(k) backlog, which existed in the early 1990s, no longer exists; it was virtually eliminated in Fiscal Year 1995. The time to first action for 510(k)s is now 90-days in almost every case, in accordance with the statute.

Overall, CDRH has shortened review times significantly, without sacrificing the necessary scientific and medical rigor of the reviews. We perceive a number of opportunities to improve our performance, and we are steadily moving in the right direction.

**CONCLUSION**

Thank you, Mr. Chairman, for the opportunity to tell you about our medical device program. In parting, let me assure you, we at the FDA are committed to a scientifically sound regulatory environment that will provide Americans with the best medical care and that will foster a vigorous domestic device industry. This includes continued services to small manufacturers, readily available guidance on our requirements, predictable and reasonable response times on applications for marketing, and equitable enforcement. But in the public interest, this commitment to the industry must be coupled with a reciprocal commitment: that medical device firms will meet high standards

in the design, manufacture, and evaluation of their products. We recognize that this can only be attained through a collaborative effort--between FDA and industry--grounded in mutual respect and responsibility. The protections afforded the American consumer, and the benefits provided the medical device industry, cannot be underestimated.